IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	**Master File No. 2:12-MD-02327** **MDL 2327** **JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**
THIS DOCUMENT RELATES TO: **WAVE 1 CASES**	

DEFENDANTS' REPLY IN SUPPORT OF MOTION TO LIMIT THE TESTIMONY OF PROF. DR. MED. UWE KLINGE

INTRODUCTION

Plaintiffs served two Rule 26 expert reports prepared by Dr. Klinge, one concerning the PROLENE* Mesh ("PROLENE* Mesh Report") used in mid-urethral slings manufactured by Ethicon and a second relating to the PROLENE* Soft Mesh ("PROLENE* Soft Mesh Report") used in Ethicon's pelvic organ prolapse products. Following Dr. Klinge's lead, Ethicon distinguished his opinions regarding PROLENE* from his opinions regarding PROLENE* Soft, challenging the reliability of each based on the support provided in his separate reports and in his depositions concerning each mesh.

Plaintiffs now claim "Ethicon makes a distinction without a difference" insofar as both PROLENE* and PROLENE* Soft "are constructed from Ethicon's polypropylene." Pls.' Resp. 10. Plaintiffs insist that any support Dr. Klinge provides for his opinions regarding PROLENE* applies equally to his opinions regarding PROLENE* Soft. And they haphazardly cite prior opinions from this Court involving one product as conclusive support for the reliability of Dr. Klinge's opinions regarding the other product.

Plaintiffs are wrong. PROLENE* and PROLENE* Soft are distinct, and those distinctions make a difference. The meshes have different pore sizes and weights, two design characteristics at the heart of Dr. Klinge's opinions. When the reliability of Dr. Klinge's opinions against each mesh is assessed individually—as it should be—it becomes clear that many of his opinions simply lack any support. For that reason, and for the other reasons set forth below, Ethicon's motion to limit Dr. Klinge's testimony should be granted.[1]

ARGUMENT

I. Dr. Klinge should not be permitted to testify that Ultrapro is a safer alternative to PROLENE* or PROLENE* Soft because he cannot testify that it would be equally effective.

Plaintiffs' claim that a mesh like Ultrapro – which has some absorbable fibers – would work in a TVT device is inherently speculative. Neither Ethicon, nor Dr. Klinge, nor the Plaintiffs have ever made a TVT out of Ultrapro and tested it, not even in a cadaver. And when Ethicon tried to make a device out of a mesh like Ultrapro, TVTO-PA, the FDA refused in 2011 to allow it to be marketed because there was inadequate evidence to support the safety and effectiveness necessary for clearance. When the device flunked Ethicon's cadaver tests, it ended the project. Plaintiffs' experts have many theories about why a larger pore mesh might be safer, but they have no evidence that it would be effective.[2] There is a difference between window screen and chicken wire.

[1] As Plaintiffs correctly point out, however, Ethicon inadvertently included in its motion and supporting memorandum a challenge to Dr. Klinge's opinions regarding effective porosity. Ethicon recognizes that this Court has previously addressed that issue and, for that reason, withdraws any challenge to Dr. Klinge's effective porosity opinions.

[2] TVT mesh has the largest pore size of any mesh sold to treat SUI in the United States (and perhaps, the world).

Plaintiffs first contend that Dr. Klinge has a reliable basis for his opinion that Ultrapro mesh is a safer alternative design, citing as support a 2013 journal article by Okulu about a single experiment in Turkey.[3] They also maintain that the Court should disregard Dr. Klinge's "reservations about the use of Ultrapro" and admit his opinion at trial. Pls.' Resp. 5–6.[4]

Although the Okulu article—which, again, is the only source Dr. Klinge has identified to support his opinion that Ultrapro might actually be effective in treating stress urinary incontinence—did involve a comparison of Ultrapro and PROLENE*, the authors of that study employed a different surgical technique described as a "double-forced sling." *See* Ex. I, Okulu et al., *supra.* at 217–224. The surgery was different, the method of implantation was different, and the operation, unlike the TVT devices, required a general anesthetic and overnight stay in the hospital. Furthermore, the authors acknowledged that "[t]his surgical method also *needs evaluation*, especially in comparison with the traditional TVT sling procedure." *Id.* at 223. Because the Okulu study did not involve the same surgical technique as the sling devices manufactured by Ethicon, Dr. Klinge cannot rely on that study as support for his opinion that Ethicon's devices would be safer if Ethicon used Ultrapro rather than PROLENE* mesh.

Dr. Klinge admitted as much in deposition, testifying that he believes Ultrapro is safe and effective when used in the manner described in the Okulu article, but not if it were to be used in the same manner PROLENE* mesh is used in Ethicon's devices:

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[3] Ex. I, Okulu et al., *Use of three types of synthetic mesh material in sling surgery: A prospective randomized clinical trial evaluating effectiveness and complications*, 47 SCANDINAVIAN J. UROLOGY 217 (2013).

[4] Plaintiffs also note that whether a plaintiff must prove safer alternative design in the first place is an unsettled issue in West Virginia. Pls.' Resp. 5. That point, even if true, is irrelevant for purposes of Ethicon's motion. If Dr. Klinge intends to testify as an expert about a particular issue, his opinion on that issue must be reliable under Rule 702, irrespective of whether or not the issue is a part of the plaintiff's *prima facie* case.

> That the treatment has to be – you have to differentiate in what form you want to have it. If you're using the ULTRAPRO to – to serve as a ligament, as the PROLENE is intended to use, then you have the problem of the pore collapse. So the large-pore ULTRAPRO becomes a small-pore mesh device with all the risks.
>
> If you use it like the Turkish people [i.e., the authors of the Okulu study], and in fact at that time point I didn't have the idea that someone is using it in a different way. If you are using it to reinforce the tissues, as we did it with the flat meshes, then you don't have the risk for pore collapse, as with the ligaments, and with this procedure maybe it is a good idea to have it. But to use it as a ligament it's not a good idea, and as a ligament I don't want to have it.

Ex. 9 to Pls.' Resp., Klinge 11/4/15 Dep. Tr. 285:5–20. And his opinion as to "safety" simply ignores the more extensive anesthesia, surgery, and hospital stay the patients in the Okalu study had to endure.

In short, Okulu, which did not involve a TVT device, does not stand for the proposition that Ultrapro, when employed like the PROLENE* mesh in Ethicon's TVT devices, is safe and effective at treating stress urinary incontinence. As a result, Dr. Klinge is "not able to predict" whether "in the specific function of a sling the Ultrapro really over the time will work really better or whether it will create some new problems." Ex. D to Ethicon's Motion, Klinge 10/5/15 Dep. Tr. 92:17–93:4. The Court should preclude him from offering any opinions he admits are speculative.

Finally, Plaintiffs ask the Court to disregard Dr. Klinge's prior testimony that Ultrapro—whether used for pelvic organ prolapse or stress urinary incontinence—is subject to the same criticisms he levies against PROLENE* and PROLENE* Soft. In other words, Dr. Klinge has admitted that Ultrapro, by definition, is not a safer and feasible alternative. Dr. Klinge has not merely contradicted himself, as Plaintiffs now suggest. *See* Pls.' Resp. 6. Rather, Dr. Klinge has repeatedly and steadfastly testified that Ultrapro is neither safe nor effective at treating stress urinary incontinence when implanted in the same manner as PROLENE* mesh in TVT. *See id.*

(testifying that using Ultrapro the way PROLENE* mesh is intended to be used is "not a good idea" because it "becomes a small-pore mesh device with all the risks"); *see also* Ex. E to Ethicon's Motion, Klinge 11/15/13 Dep. Tr. 529:12–23 (testifying that Ultrapro "is not sufficient to withstand—or to preserve the big pores—under these conditions of biomechanics as it is required for the use as a sling"). The jury should not be permitted to hear testimony Dr. Klinge has admitted for years is untrue.

Notably, Plaintiffs say nothing about PROLENE* Soft. *See, e.g.*, Pls.' Resp. 5 ("In his most recent deposition, Dr. Klinge identified Ultrapro as a mesh superior to Prolene . . . ."); *id.* at 6 ("Dr. Klinge has thoroughly explained why a lighter-weight, larger pore mesh like Ultrapro reduces the risk of certain injuries as compared to Prolene"). Nowhere in Dr. Klinge's report, his deposition testimony, nor in Plaintiffs' response brief is there any basis for Dr. Klinge's opinion that a lighter-weight, larger-pore mesh like Ultrapro would be more feasible, safer, and more effective in treating pelvic organ prolapse than PROLENE* Soft. Dr. Klinge testified in *Bellew*[5], a Prolift case, that he is not aware of any peer reviewed studies showing that any proposed alternative to PROLENE* Soft is safer and more effective at treating pelvic organ prolapse. *See* Ex. G. to Ethicon's Motion, Klinge 11/10/14 Dep. Tr. 182:14–184:2.

This Court recognized this same deficiency in *Bellew*, observing that "Dr. Klinge fails to cite *any* peer-reviewed studies" to support his opinions on alternative design. Mem. Op. & Order (*Daubert* Motions) 16, *Bellew v. Ethicon, Inc.*, No. 2:13-cv-22473, 2014 WL 6680356 (S.D.W. Va. Nov. 25, 2014). The Court precluded Dr. Klinge from testifying about safer alternatives because his report "provides no indication that his alternative design opinions are based on anything other than his and Dr. Mühl's effective porosity testing and internal Ethicon

[5] *Bellew v. Ethicon, Inc.*, No. 2:13-cv-22473, 2014 WL 6680356 (S.D.W. Va. Nov. 25, 2014).

documents," which were "not sufficiently reliable scientific bases under *Daubert*." Dr. Klinge's PROLENE* Soft Mesh Report is identical to his report in *Bellew*, and his alternative design opinions should be excluded for the same reason.

II. Dr. Klinge should not be permitted to testify that PVDF is a safer alternative to PROLENE* or PROLENE* Soft.

Plaintiffs next respond that Dr. Klinge has offered a reliable basis for his opinion that PVDF is a safer alternative to the meshes used by Ethicon. Again, Plaintiffs have failed to distinguish between PROLENE* and PROLENE* Soft.

Although Dr. Klinge attempts to provide support for his opinion that PVDF is a safer alternative to PROLENE*, Plaintiffs cannot overcome the fact that Dr. Klinge has never examined whether PVDF is subject to the same deficiencies he identifies in PROLENE*. *See* Ex. D to Ethicon's Motion, Klinge 10/5/15 Dep. Tr. 95:15-24 (testifying he does not know whether PVDF is subject to particle loss). Dr. Klinge has also failed to identify <u>any</u> peer-reviewed literature showing that PVDF is equally effective as PROLENE* in the treatment of stress urinary incontinence. His opinion should be excluded as unreliable.

With respect to the Prolene Soft, , Dr. Klinge's report includes just one sentence about PVDF: "The PVDF product, Dynamesh, is a safer design than Gynemesh PS for all of the reasons stated above as further established in Mühl's testing." *See* Ex. C to Ethicon's Motion, PROLENE* Soft Mesh Report 16. He never identifies "the reasons stated above," nor does he provide any other support (other than internal company documents) for his opinion. As the Court recognized in *Bellew*, the testing by Dr. Mühl and the Ethicon documents are "not sufficiently reliable scientific bases under *Daubert*." Mem. Op. & Order (*Daubert* Motions) 16, *Bellew v. Ethicon, Inc.*, No. 2:13-cv-22473, 2014 WL 6680356 (S.D.W. Va. Nov. 25, 2014). Just as it did in *Bellew*, the Court should again preclude Dr. Klinge from testifying about PVDF as a safer

alternative to PROLENE* Soft.

III. Dr. Klinge should not be permitted to testify about degradation of PROLENE

Plaintiffs continue their bait-and-switch routine in responding to Ethicon's challenges to Dr. Klinge's opinions regarding degradation, particle loss, and fraying, again referring generally to Dr. Klinge's opinions and testimony rather than distinguishing between the bases for his opinions regarding PROLENE* and PROLENE* Soft.

Although Ethicon is content to rely on its motion and supporting memorandum on this issue, it is worth noting that the following points are uncontroverted. First, Dr. Klinge's opinions regarding degradation, particle loss, and fraying are relevant only insofar as another expert testifies that the PROLENE* or PROLENE* Soft mesh implanted in each plaintiff actually degraded, frayed, and lost particles *in vivo*.

Second, Dr. Klinge identifies only three bases for his opinion that PROLENE* Soft mesh frays and loses particles: (1) several internal company documents relating to TVT, a mid-urethral sling that uses PROLENE* mesh rather than PROLENE* Soft; (2) a 2003 study by Pariente describing "particle shedding" in TVT; and (3) a "Prolift implantation video." *See* Ex. C to Ethicon's Motion, PROLENE* Soft Mesh Report 19–23. Notably, Dr. Klinge does not address the fact that PROLENE* Mesh can be cut mechanically, whereas PROLENE* Soft is cut ultrasonically. These bases, alone or together, are insufficient to support his opinion. Dr. Klinge should be precluded from testifying about alleged fraying and particle loss of PROLENE* Soft.

Third, Plaintiffs acknowledge that the FDA approved the PROLENE* suture. The Court should not permit Plaintiffs to offer expert testimony that the PROLENE* suture degrades, while at the same time precluding Ethicon from introducing evidence that the FDA has deemed the PROLENE* suture safe and effective, perhaps because the same evidence shows that the one-

micron degradation, if it exists, has no adverse clinical consequences.

CONCLUSION

WHEREFORE, FOR THESE REASONS and as more fully set forth in Ethicon's motion and supporting memorandum of law, Ethicon respectfully requests that this Court enter an order granting its Motion to Limit the Testimony of Prof. Dr. Med. Uwe Klinge.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I certify that on May 13, 2016, I electronically filed this document with the clerk of the court using the CM/ECF system, which will send notification of this filing to CM/ECF participants registered to receive service in this MDL.

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